

## SUBCHAPTER A—GENERAL PROVISIONS

### PART 1 [RESERVED]

### PART 2—CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

#### Subpart A—Introduction

Sec.

- 2.1 Statutory authority for confidentiality of substance use disorder patient records.
- 2.2 Purpose and effect.
- 2.3 Criminal penalty for violation.
- 2.4 Reports of violations.

#### Subpart B—General Provisions

- 2.11 Definitions.
- 2.12 Applicability.
- 2.13 Confidentiality restrictions and safeguards.
- 2.14 Minor patients.
- 2.15 Incompetent and deceased patients.
- 2.16 Security for records.
- 2.17 Undercover agents and informants.
- 2.18 Restrictions on the use of identification cards.
- 2.19 Disposition of records by discontinued programs.
- 2.20 Relationship to state laws.
- 2.21 Relationship to federal statutes protecting research subjects against compulsory disclosure of their identity.
- 2.22 Notice to patients of federal confidentiality requirements.
- 2.23 Patient access and restrictions on use.

#### Subpart C—Disclosures with Patient Consent

- 2.31 Consent requirements.
- 2.32 Prohibition on re-disclosure.
- 2.33 Disclosures permitted with written consent.
- 2.34 Disclosures to prevent multiple enrollments.
- 2.35 Disclosures to elements of the criminal justice system which have referred patients.
- 2.36 Disclosures to prescription drug monitoring programs.

#### Subpart D—Disclosures without Patient Consent

- 2.51 Medical emergencies.
- 2.52 Research.
- 2.53 Audit and evaluation.

#### Subpart E—Court Orders Authorizing Disclosure and Use

- 2.61 Legal effect of order.
- 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.
- 2.63 Confidential communications.
- 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.
- 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.
- 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a part 2 program or the person holding the records.
- 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a part 2 program.

AUTHORITY: 42 U.S.C. 290dd-2.

SOURCE: 82 FR 6115, Jan. 18, 2017, unless otherwise noted.

#### Subpart A—Introduction

##### § 2.1 Statutory authority for confidentiality of substance use disorder patient records.

Title 42, United States Code, Section 290dd-2(g) authorizes the Secretary to prescribe regulations. Such regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this statute, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

##### § 2.2 Purpose and effect.

(a) *Purpose.* Pursuant to 42 U.S.C. 290dd-2(g), the regulations in this part impose restrictions upon the disclosure and use of substance use disorder patient records which are maintained in connection with the performance of any part 2 program. The regulations in this part include the following subparts:

## § 2.3

(1) Subpart B of this part: General Provisions, including definitions, applicability, and general restrictions;

(2) Subpart C of this part: Disclosures with Patient Consent, including disclosures which require patient consent and the consent form requirements;

(3) Subpart D of this part: Disclosures without Patient Consent, including disclosures which do not require patient consent or an authorizing court order; and

(4) Subpart E of this part: Court Orders Authorizing Disclosure and Use, including disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders.

(b) *Effect.* (1) The regulations in this part prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstance exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) The regulations in this part are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment.

(3) Because there is a criminal penalty for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers v. United States*, 327 U.S. 614, 621–22, 66 S. Ct. 705, 707–08 (1946)).

### § 2.3 Criminal penalty for violation.

Under 42 U.S.C. 290dd–2(f), any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with Title 18 of the U.S. Code.

### § 2.4 Reports of violations.

(a) The report of any violation of the regulations in this part may be di-

## 42 CFR Ch. I (10–1–20 Edition)

rected to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of the regulations in this part by an opioid treatment program may be directed to the United States Attorney for the judicial district in which the violation occurs as well as to the Substance Abuse and Mental Health Services Administration (SAMHSA) office responsible for opioid treatment program oversight.

## Subpart B—General Provisions

### § 2.11 Definitions.

For purposes of the regulations in this part:

*Central registry* means an organization which obtains from two or more member programs patient identifying information about individuals applying for withdrawal management or maintenance treatment for the purpose of avoiding an individual's concurrent enrollment in more than one treatment program.

*Diagnosis* means any reference to an individual's substance use disorder or to a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment.

*Disclose* means to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person.

*Federally assisted*—see § 2.12(b).

*Informant* means an individual:

(1) Who is a patient or employee of a part 2 program or who becomes a patient or employee of a part 2 program at the request of a law enforcement agency or official; and

(2) Who at the request of a law enforcement agency or official observes one or more patients or employees of the part 2 program for the purpose of reporting the information obtained to the law enforcement agency or official.